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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,434	03/15/2001	Glenn McGall	2719.2017-001	6484

33880 7590 12/19/2003

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EXAMINER

EPPS FORD, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,434

Applicant(s)

MCGALL ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

2. Applicants are requested to provide additional copies of the IDS and Supplemental IDS previously submitted for this application, including all non-patent literature. The original copies of Applicant's IDS and Supplemental IDS were not found within the file wrapper of this application.

Claim Rejections - 35 USC § 103

3. Claims 1-3, 5-13 and 18-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Earhart et al. in view of McGall et al., for the reasons of record set forth in the Official Action mailed 5-28-03.

Applicant's arguments filed 9-02-03 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the McGall Declaration filed 3-14-03 clearly provides unexpected results for the iodine concentrations recited in the instant claims. However, contrary to Applicant's assertions, first it is noted that on page 5, last paragraph, of the Declaration filed 3-14-03 it states that the results presented are for illustrative purposes, therefore it is unclear if the data presented is truly representative of the full range of concentrations claimed by Applicants, particularly wherein said encompasses concentrations "from about 0.005." The hybridization intensities set forth in the Declaration do not provide a direct correlation between reduction in iodine concentration and increase in hybridization signal intensity. For example, based upon Applicant's assertions one of ordinary skill in the art would

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expect the hybridization signal intensity for 0.01 M to greater than that expected for 0.02 M, however it is significantly lower than that observed for 0.02M.

As stated previously, there is no data provided which indicates that iodine concentrations having values ranging from about 0.005 M to about 0.05M would have unexpected hybridization intensity values as compared to the commonly used concentrations of about 0.1 M iodine in the claimed method. Since the margin of error is not provided for the observed values of hybridization intensity, absent evidence to the contrary, the values observed using a concentrations of 0.1M iodine in the claimed method would not be considered statistically different from those observed using 0.01M, or 0.05M.

Furthermore, since the specification as filed does not provide a clear definition of the term “about” as recited in the claimed ranges, the metes and bounds of the range “from about 0.005M to about 0.05M,” is unclear. The McGall Declaration does not provide any evidence that concentrations that are “about 0.005” or “about 0.10M” would produce unexpected results when practicing the claimed method. At best, it appears that the McGall Declaration provides unexpectedly higher hybridization intensity values for only one concentration, 0.02M.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 18 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter Rejection), for the reasons of record set forth in the Official Action mailed 5-28-03.

Applicant's arguments filed 9-02-03 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the range recited in claim 18, namely "from about 0.01M to about 0.05M" clearly comply with the description requirement. Applicants refer to MPEP § 2163.05 as support for their amendment. However, unlike the situation set forth in this section of the MPEP the specific example of the limitation "36%" provided support forth the amendment "between 35% and 60," the example given in the MPEP did not provide support for a range "from about 35%," as compared to the instant case wherein the limitation "from about 0.01M" is 2 fold lower than 0.02M and clearly includes ranges less than 0.01M. It is unclear how the disclosure of 0.02M would inherently disclose ranges that are two-fold less than 0.02M, therefore the range "from about 0.01M to about 0.05M," can not be considered to comply with the written description requirement.

As stated in the prior Office Action, the limitation, "from about 0.01M to about 0.05M," is considered new matter since one of skill in the art would not consider this limitation to be inherently supported by the discussion in the original disclosure. See MPEP § 2163.06, which states "The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement."

Applicants must remove the new matter set forth in claim 18 in response to this Office Action.

6. Claims 1-19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the Official Action mailed 5-28-03.

7. Applicant's arguments filed 9-02-03 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the claimed ranges clearly delineate the bounds of the invention and that a potential infringer could readily (*determine*) whether a particular method was encompassed by the instant claims (i.e., by determining the iodine concentration). Applicants assert that the instant claims present a situation analogous to *ex parte Eastwood* and *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, wherein the term "about" was held to be a definite limitation because infringement could be clearly assessed through the use of a stop watch. In the instant case, Applicants argue that like *W.L. Gore & Associates*, infringement can be readily assessed by measuring the concentration of iodine in solution (e.g., via spectrophotometric methods). However, the facts set forth in the *W.L. Gore & Associates* case do not specifically correlate with the current facts of the instant application since there is nothing in the specification, prosecution or the prior art to provide any indication as to what range of specific activity is covered by the term "about." The prior art shows that ranges that are 2 times greater than the upper limit of Applicant's range are expected to possess activity. However, it is unclear what other concentrations of iodine would also possess the ability to oxidize a phosphite ester linkage to a phosphate ester linkage. Therefore, since Applicant's have not defined the range of specific activity that is covered by the term "about" as used in the context of the instant claims, the ordinarily skilled artisan would not be

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able to determine the full scope of iodine concentrations that are encompassed by the range “from about 0.005 M to about 0.05 M.”

Conclusion

8. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 14-17 are allowable over the prior art of record since Applicants have demonstrated unexpected results using 0.02 M iodine in the claimed methods, see the Declaration filed 3-14-03.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

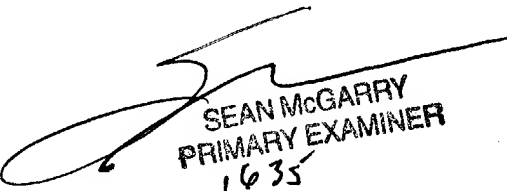
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE

December 12, 2003


SEAN MCGARRY
PRIMARY EXAMINER
1635